

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER: Stuart, C. W.

TITLE: DEVICE AND METHOD FOR TEMPERING AND HUMIDIFYING GAS,
ESPECIALLY RESPIRATORY AIR

Amendment B: REMARKS

Upon entry of the present amendments, previous Claims 11 -20 have been canceled and new Claims 21 - 24 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of placing the claim language into a more proper U.S. format and also for the purpose of more clearly distinguishing the present invention from the prior art.

In the Office Action, Claims 11 - 15 and 18 were rejected under 35 U.S.C. § 102(b) as anticipated by the Smith patent. Claims 11, 16 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hitzler patent in view of the Thudor publication. Claims 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Smith patent in view of the Brossman patent. The specification was objected to as failing to describe the "circulating drive means". Claims 11 - 17 and 19 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

As an overview to the present reply, Applicant has amended previous independent Claim 11 in the form of new independent Claim 21. In new independent Claim 21, we have described the

system for heating and humidifying a gas as being "for delivery to a patient". The fluid reservoir is now indicated as having a "fluid therein". The humidification chamber is now indicated as having a gas inlet at a lower portion of the humidification chamber. The gas outlet is being recited as being positioned "at a level above said gas inlet". Additionally, it is recited that the humidification chamber has a "filling material" therein and positioned between the gas inlet and the gas outlet. The "circulation drive means" has been replaced with the term "pumping means" so properly reflect the language in the specification for reference under 35 U.S.C. § 112(6). It is now recited that the pumping means passes the fluid from the fluid reservoir "into an upper portion of said humidification chamber" such that the fluid flows downwardly therefrom and into the filling material. The "gas supplying means" is now positively recited. This "gas supplying means" serves to pass a gas through the gas inlet and into the humidification chamber such that the gas flows upwardly through the filling material so as saturate the gas with fluid and without aerosol formation. It is further recited that the gas "flows outwardly of said humidification chamber through said gas outlet and to the patient". Applicant contends that these features serve to distinguish the present invention from prior art references.

Dependent Claims 22 and 23 correspond, respectively, to the limitations of previous dependent Claims 12 and 13. Dependent Claim 24 reflects the limitations of previous dependent Claim 15. Applicant has canceled previous Claims 14 and 16 - 20 herein.

Relative to the prior art Smith patent, Applicant respectfully contends that independent Claim 21 is not anticipated by this prior art reference. Fundamentally, the Smith patent describes a pressure-type nebulizer. The nebulizer carries out its function by having a gas inlet that works, with a venturi effect, so as to draw the fluid from a fluid reservoir into the humidification chamber. The

nebulized fluid is then passed through an outlet. An anvil 19 is provided within the humidification chamber so as to vary a size of the droplets being carried outward of the gas outlet.

Unlike the present invention, as now claimed, there is no gas inlet located in a lower portion of the humidification chamber. The humidification chamber does not have a "filling material" therein which is positioned between the gas inlet and the gas outlet. Although there is a "pumping means" in the Smith patent, this does not serve to pass the fluid from the fluid reservoir into "an upper portion of the humidification chamber" such that the "fluid flows downwardly therefrom and into the filling material". The "gas supplying means" in the Smith patent does not cause the gas to flow upwardly "through the filling material so as to saturate the gas with fluid and without aerosol formation". On this basis, Applicant respectfully contends that the present invention, as defined by independent Claim 21, is not anticipated by this prior art Smith patent.

In the Smith patent, the control heater does not heat the fluid but, heats the gas/nebulized fluid mixture. The heating of the gas/nebulized or evaporated fluid mixture has the disadvantage that this mixture can be easily overheated. Any overheating of the gas will be harmful to a patient. Additionally, it is very difficult to heat a gas in a proper way in order to avoid overheating the gas. In contrast, since the present invention heats the fluid to a predetermined temperature, it is relatively easy to control the temperature of the gas while, at the same time, ensuring that the gas is not overheated.

The pressure-type nebulizer of the Smith patent is part of the prior art that was described in paragraph [0030] of the original specification as follows:

Those devices nebulize a fluid resulting in the formation of tiny droplets, not molecular fluid. Thus those devices inherit the same disadvantages as ultrasound-type nebulizers.

Also, the problems with the such ultrasound-type nebulizers were recited in the original specification in paragraph [0028] as follows:

Those devices use ultrasound to induce fluid vibrations resulting in the generation of tiny droplets which enter the gas flow. Main disadvantage of that design is that the “humidification” doesn’t result in molecular fluid within the gas but in substantially larger fluid particles (generation of an aerosol). In contrast to molecular fluid, those larger particles have the potential to transport pathogens to the patient. There is also the risk that – especially with intermittent or varying gas flow – the amount of humidity is too high or too low.

As such, the system of the present invention avoids this problem by heating the fluid to a desired temperature and then, through a heat exchange relationship and through a direct contacting relationship, passing that temperature to the gas. Since the gas is flowing through the heated fluid, the gas is properly saturated with the fluid at a molecular level. There is no aerosol or droplets formed with the pressurized gas. As such, the present invention overcomes those problems of the prior art. In particular, these problems are further overcome by the fact that the gas flow is in an opposite direction to the flow of the liquid. Since the humidification chamber is filled with the filling material, this filling material acts as an energy buffer and inherits a large energy storage capacity. This allows the release of energy quickly to immediately provide extra energy for evaporation, if needed, to cause a gas flow in case the gas flow varies. This feature was recited in the original specification in paragraphs [0053] and [0054]. As such, Applicant respectfully contends that the Smith patent would not make obvious the present invention.

The combination of the Hitzler patent and the Thudor publication also fails to make obvious the teachings of the present invention. Fundamentally, the Hitzler patent shows a room dehumidifier (see the Abstract). The humidification chamber in the Hitzler patent does not have a filler material

therein. The gas inlet is located above the gas outlet. There is no filler material located between the gas inlet and the gas outlet. The water will enter a bottom of the humidification chamber. The water that is introduced does not flow downwardly into a filling material. As such, the construction of the Hitzler patent would be inappropriate for use for supplying humidified gas to a patient. Once again, as stated before, the Hitzler patent lacks the filling material which serves as a temperature and energy buffer. It does not have the large energy storage capacity of the present invention for the purpose of releasing energy quickly or immediately in order to provide extra energy for evaporation. Since there is no gas flow occurring in an opposite direction to the flow of the liquid, there is no direct wide surface area contact between the liquid and the gas so as to properly and quickly humidify the gas.

Applicant notes that the Thudor publication does describe a heater. If the liquid introduced into the Hitzler patent were heated, it would still flow into the bottom of the humidification chamber and would not intimately mix with the gas through the use of the filling material. On this basis Applicant respectfully contends that independent Claim 21 would not be obvious in view of this prior art combination.

Applicant has corrected the informalities identified by the Examiner in the present claim language. In particular, the "circulation drive means" has been removed and replaced with the term "pumping means". The "pumping means" is clearly described in the specification.

Based upon the foregoing analysis, Applicant contends that independent Claim 21 is now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and

allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

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Date

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